

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

## Complete if Known

Sheet	1	of	3
Application Number	10/517,812		
Filing Date	December 14, 2004		
First Named Inventor	Harald BREIVIK et al.		
Art Unit	1621		
Examiner Name	Deborah D. CARR		
Attorney Docket Number	10260.0006-00000		

## U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No.	Document Number Number-Kind Code <sup>2</sup> (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US-2,126,467	08-09-1938	Hickman et al.	
	2.	US-3,082,228	03-19-1963	Sutherland	
	3.	US-4,554,107	11-19-1985	Takao	
	4.	US-5,106,542	04-21-1992	Traitler et al.	
	5.	US-5,243,046	09-07-1993	Traitler et al.	
	6.	US-5,340,602	08-23-1994	Hoche	
	7.	US-5,374,751	12-20-1994	Cheng et al.	
	8.	US-5,792,795	08-11-1998	Buser et al.	
	9.	US-5,948,818	09-07-1999	Buser et al.	
		US-			
		US-			

**Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.**

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
	10.	EP 0 255 824 B1	01-24-1990	Norsk Hydro A.S.		
	11.	WO 90/12509	11-01-1990	Hoche		Abstract; English equivalent

## NONPATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>
	12.	ACKMAN, R.G. et al., "The "basic" fatty acid composition of Atlantic fish oils: Potential similarities useful for enrichment of polyunsaturated fatty acids by urea complexation," <i>J. Am. Oil Chem. Soc.</i> (1988) vol. 65, pp. 136-138.	
	13.	Azhgikhin, I.S. et al., "Obtainment of an esters concentrate of the eicosapentaenoic and docosapentaenoic as a possible substitute of arachidonic and linolenic," Pansovietic Institute, Moscow, dated March 14, 1978.	Yes
	14.	BANG, H.O. et al., "Plasma lipid and lipoprotein pattern in Greenlandic West-coast Eskimos," <i>Lancet</i> (1971) vol. 1, pp. 1143-1145.	
	15.	BRONGSHEET-SCHOUTE, H.C. et al., "The effect of various intakes of $\omega$ 3 fatty acids on the blood lipid composition in healthy human subjects," <i>Am. J. Clin. Nutr.</i> (1981) vol. 34, pp. 1752-1757.	
	16.	CONNOR, W.E., "Effects of omega-3 fatty acids in hypertriglyceridemic states," <i>Seminars in Thrombosis and Hemostasis</i> (1988) vol. 14, pp. 271-284.	
	17.	DATABASE WPI: Week 199010, Derwent Publications Ltd., JP 2025447. 01-1990	
	18.	EPAX product information (6 pages) 2008	
	19.	ERITSLAND, J. et al., "Effects of highly concentrated omega-3 polyunsaturated fatty acids and acetylsalicylic acid, alone and combined, on bleeding time and serum lipid profile," <i>J. Oslo City Hosp.</i> (1989), vol. 39, pp. 97-101.	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				<b>Complete if Known</b>	
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20.	ERITSLAND, J. et al., "The effect of Omacor™ in patients with hypertriglyceridaemia having undergone coronary artery bypass grafting," Final Report, Pronova Biocare, 1994.	
21.	"Fish oil, rich in omega-3 acids," European Pharmacopoeia 5.0 (2004) pp. 1595-1598.	
22.	HARRIS, W.S. et al., "The comparative reductions of the plasma lipids and lipoproteins by dietary polyunsaturated fats: Salmon oil versus vegetable oils," <i>Metabolism</i> (1983), vol. 32, pp. 179-184.	
23.	HIRAI, A. et al., "Effect of oral administration of highly purified eicosapentaenoic acid and docosahexaenoic acid on platelet function and serum lipids in hyperlipidemic patients," <i>Adv. Prostag. Thromb. L.</i> (1989) vol. 19, pp. 627-631.	
24.	HOLUB et al., "Alterations in molecular species of cholesterol esters formed via plasma lecithin - cholesterol acyltransferase in human subjects consuming fish oil," <i>Atherosclerosis</i> (1987) vol. 66, pp. 11-18.	
25.	JOSEPH, J., Ed. "Biomedical Test Materials Program: Production Methods and Safety Manual," NOAA Technical Memorandum NMFS-SEFC-234, pp. 1-3, Oct. 1989.	
26.	KANTHA, S.S., "Dietary effects of fish oils on human health: A review of recent studies," <i>Yale J. Biol. Med.</i> (1987) vol. 60, pp. 37-44.	
27.	KOBATAKE, Y. et al., "Dietary effect of $\omega$ -3 type polyunsaturated fatty acids on serum and liver lipid levels in rats," <i>J. Nutr. Sci. Vitaminol.</i> (1983) vol. 29, pp. 11-21.	
28.	KOBATAKE, Y. et al., "Differential effects of dietary eicosapentaenoic and docosahexaenoic fatty acids on lowering of triglyceride and cholesterol levels in the serum of rats on hypercholesterolemic diet," <i>J. Nutr. Sci. Vitaminol.</i> (1984) vol. 30, pp. 357-372.	
29.	LARSEN, L.N. et al., "Heneicosapentaenoate (21:5n-3): Its incorporation into lipids and its effects on arachidonic acid and eicosanoid synthesis," <i>Lipids</i> (1997) vol. 32, pp. 707-714.	
30.	LEAF, A. et al., "Cardiovascular effects of n-3 fatty acids," <i>New Eng. J. Med.</i> (1988) vol. 318, pp. 549-557.	
31.	Lovaza™ marketing information (2 pages) 2007	
32.	Maxepa® product information (3 pages) 1987	
33.	Medline Plus, "Triglycerides," U.S. National Library of Medicine and National Institutes of Health, 2008.	
34.	MEHTA, J.T. et al., "Dietary supplementation with omega-3 polyunsaturated fatty acids in patients with stable coronary heart disease," <i>Am. J. Med.</i> (1988) vol. 84, pp. 45-52.	
35.	MORISAKI, N. et al., "In vivo effects of cis-5,8,11,14,17-20:5 (n-3) and cis-4,7,10,13,16,19-22:6 (n-3) on serum lipoproteins, platelet aggregation, and lipid metabolism in the aorta of rats," <i>Tohoku J. Exp. Med.</i> (1983) vol. 141, pp. 397-405.	
36.	MUELLER, B.A. et al., "Biological mechanisms and cardiovascular effects of omega-3 fatty acids," <i>Clin. Pharmacy</i> (1988) vol. 7, pp. 795-807.	
37.	NESTEL, P.J. et al., "Suppression by diets rich in fish oil of very low density lipoprotein production in man," <i>J. Clin. Invest.</i> (1984) vol. 74, pp. 82-89.	
38.	PHILLIPSON, B.E. et al., "Reduction of plasma lipids and lipoproteins in hyperlipidemic patients by dietary $\omega$ -3 fatty acids," <i>Am. J. Clin. Nutr.</i> (1981) vol. 34, p. 629.	
39.	RATNAYAKE, W.M.N. et al., "Preparation of omega-3 PUFA concentrates from fish oils via urea complexation," <i>Fat Sci. Technol.</i> (1988), vol. 90, pp. 381-386.	
40.	Rote Liste, Eicosapen information, 1987.	No
41.	SANDERS, T.A.B., "The importance of eicosapentaenoic and docosahexaenoic acids," Ch. 7, pp. 101-116, in <i>The Role of Fats in Human Nutrition</i> , F.B. Padley et al., Eds., Ellis Horwood Ltd., Chichester, England, 1985.	
42.	SANDERS, T.A.B. et al., "A comparison of the influence on plasma lipids and platelet function of supplements of $\omega$ -3 and $\omega$ -6 polyunsaturated fatty acids," <i>Br. J. Nutr.</i> (1983) vol. 50, pp. 521-529.	
43.	SANDERS, T.A.B. et al., "The influence of different types of $\omega$ -3 polyunsaturated fatty acids on blood lipids and platelet function in healthy volunteers," <i>Clinical Science</i> (1983) vol. 64, pp. 91-99.	
44.	SAYNOR, R. et al., "The long-term effect of dietary supplementation with fish lipid concentrate on serum lipids, bleeding time, platelets and angina," <i>Atherosclerosis</i> (1984) vol. 50, pp. 3-10.	
45.	SIMONS, L.A. et al., "On the effects of dietary n-3 fatty acids (Maxepa) on plasma lipids and lipoproteins in patients with hyperlipidaemia," <i>Atherosclerosis</i> (1985) vol. 54, pp. 75-88.	
46.	SIMOPOULOS, A.P., "Omega-3 fatty acids from fish and fish oils: Nutritional and health effects," <i>Epithorese Kinkes Farmakologias Kai Farmakokinetikes, Int. Ed.</i> (1987) vol. 1, pp. 23-31.	
47.	SMITH, P. et al., "Influence of highly concentrated n-3 fatty acids on serum lipids and hemostatic variables in survivors of myocardial infarction receiving either oral anticoagulants or matching placebo," <i>Thromb. Res.</i> (1989) vol. 53, pp. 467-474.	

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				<b>Attorney Docket Number</b>	10260.0006-00000

**NONPATENT LITERATURE DOCUMENTS**

48.	SWANSON, D.R., "Fish oil, Raynaud's Syndrome, and undiscovered public knowledge," <i>Perspect. Biol. Med.</i> (1986) vol. 30, pp. 7-18.	
49.	TURCHETTO, E. et al., "Protective role of vitamin E on essential fatty acids," <i>Acta Vitaminol. Enzymol.</i> (1982) vol. 4, pp. 267-277.	Abstract
50.	VON LOSSONCZY, T.O. et al., "The effect of a fish diet on serum lipids in healthy human subjects," <i>Am. J. Clin. Nutr.</i> (1978) vol. 31, pp. 1340-1346.	

Examiner Signature	/Deborah D Carr/	Date Considered	12/30/2009
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